

## REMARKS

This application pertains to a novel solid active ingredient formulation.

Claims 1, 3, 4 and 6-15 are pending, claims 2 and 5 being cancelled by this amendment. The limitations of claim 2 have been added to claim 1. Claims 7-10, 14 and 15 have been withdrawn from consideration as drawn to a non-elected invention, so that the claims under consideration are claims 1, 3, 4, 6 and 11-13.

The Examiner has imposed a three-way restriction requirement, between claims 1-6 and 11-13, drawn to the process (denoted Group I by the Examiner); claims 7-9 and 14-15, drawn to predominantly amorphous active substance formulations (denoted Group II by the Examiner) and claim 10, drawn to crop protection agents (denoted Group III) by the Examiner). Applicants provisionally elected Group I, with traverse, and now affirm said election. The claims reading on said election are claims 1-4, 6, and 11-13.

Applicants respectfully point out, that the current application is a PCT-national phase entry of WO 2005/044221 and that an international preliminary report on patentability (IPRP, see enclosed) as well as an international search report (ISR) have been issued by the international search authority (the European Patent Office – EPO), wherein neither report raised any objection with regard to a lack of unity of invention as to Rule 13.1 PCT.

Pursuant to *Caterpillar Tractor Co. v. Commissioner of Patents and Trademarks*, 650 F. Supp. 218, 231 USPQ 590 (E.D. Va. 1986) the Examiner is bound to said determinations of the PCT and therefore should reconsider the restriction requirement in view of the opinion of the international search authority. In the corresponding national phase entry of this application in Europe, the EPO similarly did not raise any lack of unity of invention objections.

In fact, if the Examiner should insist on his opinion under Rule 13.1 PCT there would be a significant gap of understanding of the provision of the PCT-rules between EPO practice and USPTO practice.

Therefore Applicants respectfully request that the restriction requirement be withdrawn.

Should the Examiner insist on his opinion, applicants elect Group I with traverse and respectfully request that upon the allowance of claims drawn to the elected subject-matter, the non-elected claims be rejoined.

Applicants have amended claim 1 to now recite that the “solubility of the active substance A) is greater than 1 % by weight in the low molecular weight organic solvent 1”. Said amendment is supported by the disclosure of the description of the (published) application in paras [0021] and [0055], as well as by claim 5, which therefore has been cancelled.

Furthermore, Claim 1 has been amended to recite that the polymer B) is a “highly polar” polymer. Addition of said limitation is supported by the disclosure of the description of the (published) application in para [0031]. Said limitation now describes the polymer B) in a more distinct way and therefore the former limitation that the polymer B) should be readily soluble in water has been deleted, as the polarity of the polymer B) ensures said property of being “readily soluble”.

Claim 1 has further been amended to recite that in step d) a homogenous fine-particle suspension is formed.

Finally Claim 1 has been amended to make the optional “mixing nozzle” a mandatory limitation and to add that a pressure gradient is applied. Said amendment is supported by claim 2, which therefore has been deleted.

Claim 6 has been amended to obviate the concern raised by the Examiner regarding the meaning of the term “of”.

### **Rejections under 35 USC § 112 first paragraph**

Claims 1-6 are rejected under 35 U.S.C. 112 first paragraph as failing to comply with the written description requirement.

Applicants have now amended claim 1 to recite that the solvent 1 is a low molecular weight organic solvent, which should now sufficiently convey the nature of said solvent 1 to one of ordinary skill in the art.

Furthermore, Applicants have amended claim 1 to recite that the active substance A) has a solubility of greater than 1 % by weight in said solvent 1. Thus, when departing from any active substance the person of ordinary skill in the art can determine a suitable solvent from the group of said low molecular weight organic solvents and intrinsically or vice versa.

Thereafter knowing a solvent / active substance combination the person of ordinary skill in the art may choose from a very limited list of “displacement agents” having the properties of dissolving the active substance A) by less than 1% by weight while being miscible with the aforementioned organic, low molecular weight solvent to effect the precipitation.

In view of the foregoing amendments and remarks, the rejection of claims 1-6 under 35 USC 112 first paragraph should now be withdrawn, as the written description requirement is now fulfilled.

### **Rejections under 35 USC § 112 second paragraph**

Claims 1-6 and 11-13 are rejected under 35 U.S.C. 112 second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner contends that the term “predominantly amorphous polymer” is relative and therefore fails to meet the requirements of 35 U.S.C. 112, second paragraph.

The meaning of "predominantly amorphous" is defined at page 2, lines 5-8, of the specification and the meaning will therefore be very clear to those skilled in the art.

Further, Applicants respectfully submit that the Examiner obviously did not have any problem in understanding the teaching of the Runge et al. reference, wherein the term “predominantly amorphous” is used as well (see Col. 6, lines 1-3, and Claim 1). As the Runge et al. reference has been allowed by the USPTO with exactly the same terminology as used in the present application, Applicants respectfully request the Examiner to reconsider, as Applicants can not understand why the Runge et al. reference would have been allowable, while Applicants' application is rejected on the basis of the same terminology in the claims.

Furthermore, Applicants respectfully point out, that the claims need to be read in view of the description of the invention. In [0011] of the published application, Applicants explicitly define the term “predominantly amorphous”. Obviously the Runge et al. reference's and Applicants' understanding of “predominantly amorphous” is identical, as their definitions are identical as well (see Col. 6, lines 3-7).

As Applicants have amended claim 1 to recite that the Polymer B) shall be “highly polar” instead of “readily soluble in water”. Applicants believe that in view of the foregoing amendments and remarks any deficiency of claim 1 under 35 USC 112 second paragraph has been addressed and obviated.

Finally the Examiner rejects claim 6 because of the “of” after “suspension”. Applicants have amended the claim to delete the objected-to expression “of”.

It is believed that the amendments obviate the rejection, and the rejection of claims 1-6 and 11-13 under 35 U.S.C. 112 second paragraph should now be withdrawn.

### **Rejections under 35 USC § 102**

Claims 1, 4-5 and 11-13 are rejected under 35 USC 102 as being anticipated by Frank et al. (US 5,780,062).

Claim 2 is not included in this rejection, and the limitations of claim 2 have been added to claim 1 thereby making claim 1 an independent form of claim 2.

The Examiner may have overlooked that the present Claim 1 recites that the mixing needs to be performed “continuously and uniformly”. Applicants suspect that the Examiner may have thought that said limitation was optional. By virtue of the foregoing amendments made to claim 1 such misunderstanding of claim 1 should now be obviated.

Furthermore Frank et al. does not disclose the use of a nozzle to form turbulent flow.

Accordingly claim 1 cannot be seen as anticipated by the Frank et al. reference. Claims 4 and 11-13 are directly or indirectly dependent on claim 1 and thus the foregoing rejection of claims 1, 4 and 11-13 under 35 USC 102 as anticipated by Frank et al. (US 5,780,062) should now be withdrawn.

Claims 1, 4-6, and 11-13 are rejected under 35 USC 102 as being anticipated by Albayrak et al. (EP 1,344,520).

The Albayrak et al. reference discloses that the mixing zone (the vessel) according to Examples 1 to 4, as well as 6 to 9 shall be stirred at 600 rpm (see Example 1 page 7, lines 3-5). Only after having produced the final suspension is the intensity of mixing increased to a stirring speed of 6000 rpm (see Example 1, page 7, line 6).

Accordingly it is apparent from the relation of mixing speeds (being 1:10) that the mixing in the first mixing zone is non-turbulent while the second mixing might be performed under turbulent conditions. Either way the Albayrak et al. reference discloses neither a continuously and uniformly operated mixing nor use of a nozzle to form turbulent flow.

Again, claim 2 is not included in this rejection, and the limitations of claim 2 have now been incorporated into claim 1. This rejection is therefore believed obviated by the incorporation of the limitations of claim 2 into claim 1.

Accordingly the subject matter of present claim 1 cannot be seen as anticipated by the Albayrak et al. reference. Claims 4 and 11-13 are directly or indirectly dependent on claim 1 and thus the foregoing rejection of claims 1, 4 and 11-13 under 35 USC 102 as being anticipated by Albayrak et al. (EP 1,344,520) should now be withdrawn.

Claims 1-2, 4-6 and 11-13 are rejected under 35 USC 102 as being anticipated by Runge et al. (US 6,458,745).

As was the case with the Frank et al. reference and the Albayrak et al. reference, the Runge et al. reference fails to teach or suggest the use of a mixing nozzle. Even though the Runge et al. reference teaches alternatives such as stirring or shaking or even “injecting a forced stream”.

Accordingly the subject matter of present claim 1 is not anticipated by the Runge et al. reference. Claims 4, 6 and 11-13 are directly or indirectly dependent on claim 1 and thus the foregoing rejection of claims 1, 4, 6 and 11-13 under 35 USC 102 as being anticipated by Runge et al. (US 6,458,745) should now be withdrawn.

#### **Rejections under 35 USC 103 (a)**

Claims 1-6, and 11-13 are rejected under 35 USC 103(a) as being obvious over Albayrak et al. (EP 1,344,520).

As discussed above, the Albayrak et al. reference discloses neither a continuously and uniformly operated mixing operation nor the use of a nozzle to form turbulent flow.

More specifically, the Albayrak et al. reference (see above) is concerned with the formation of primary particles in a non-turbulent set-up.

Accordingly, nothing in the Albayrak reference would lead those skilled in the art to alter Albayrak's process in such a way as to arrive at a uniformly operated mixing operation using a nozzle to form turbulent flow.

Accordingly the subject matter of present claim 1 is not obvious over Albayrak et al. Claims 3-4, 6 and 11-13 are directly or indirectly dependent from claim 1 and thus the foregoing rejection of claims 1, 3-4, 6 and 11-13 under 35 USC 103 (a) as obvious over Albayrak et al. (EP 1,344,520) should now be withdrawn.

For the sake of completeness, Applicants also point out that neither of the cited references teaches or suggests use of a nozzle to form turbulent flow. Accordingly Applicants believe that a further rejection of the present claims over any combination of the foregoing cited prior art documents can not render the present invention unpatentable.

In view of the present amendments and remarks it is believed that claims 1, 3, 4 and 6-15 are now in condition for allowance. Reconsideration of said claims by the Examiner is respectfully requested and the allowance thereof is courteously solicited.

CONDITIONAL PETITION FOR EXTENSION OF TIME

If any extension of time for this amendment is required, applicants request that this be considered a petition therefore. Please charge the required petition fee to Deposit Account No. 14-1263.

ADDITIONAL FEE

Please charge any insufficiency of fee or credit any excess to Deposit Account No. 14-1263.

Respectfully submitted,  
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